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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,483	12/31/2003	Michael S. Collins	ZIM0391	1206

7590 02/12/2007
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EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/749,483

Applicant(s)

COLLINS ET AL.

Examiner

Anu Ramana

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,8-19 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-19 and 25 is/are allowed.
- 6) ☒ Claim(s) 1,3,4,8-16,21-24 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/31/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 18, 2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 8-16 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 8, the functional recitation, "to provide a separation between the male and female portions to prevent the male and female portions from locking together," renders the claim vague and indefinite. Clearly, the sleeve of Applicants' invention maintains the implant components in an assembled arrangement and locks them together.

In claim 21, the functional recitation, "to prevent the male and female portions from locking together" contradicts, "engaging the male and female portions in resilient, frictional, relative position maintaining relationship," which implies locking of the male and female portions.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Pfaff et al. (US 6,607,560).

Pfaff et al. disclose a modular joint prosthesis having a first component 3 with a female junction element 4 and a second component 2 with a male junction element 5 receivable within the female junction element and a hollow resilient sleeve 4 that is capable of being rolled upon itself in a ring-like configuration (Figs. 1 and 2, col. 2, lines 22-30, col. 3, lines 3-14 and col. 4, lines 12-36).

Claims 1, 3, 4, 8, 10, 14-16, 21, 23 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Bunz (US 6,802,866).

Bunz discloses a modular joint prosthesis having a first component 3 with a female junction element and a second component 2 with a male junction element receivable within the female junction element in a self-locking taper relationship and a hollow resilient sleeve 6 that is capable of being rolled upon itself in a ring-like configuration (Figs. 1-11, col. 3, lines 21-67 and col. 4, lines 1-21).

The method steps of claim 21 are inherently performed when the Bunz prosthesis is assembled.

Claims 8-10, 13, 14, 16, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Averill et al. (US 4,921,500).

Averill et al. disclose a modular orthopedic implant having a femoral stem or "first component" 10 with a male junction element 18 and a femoral head component or "second component" 20 with a female junction element 32 and an adaptor or "hollow sleeve" 40 with grooves 66 extending circumferentially around the outer surface 52 of the sleeve that maintain the first and second components in an assembled condition wherein the stem and head components are made of a biocompatible metal (Fig. 3, col. 3, lines 16-68, col. 4 and col. 5, lines 1-51).

The method steps of claim 21 are inherently performed when the Averill et al. modular implant is assembled together.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 11 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunz (US 6,802,866) in view of Draenert (US 6,682,566).

Bunz discloses all the elements of the claimed invention except for providing the components in a variety of sizes in kit form so that the components can be custom fitted to a patient during a surgical procedure.

Draenert teaches providing a modular prosthesis with components having different sizes so that the prosthesis can be assembled for a specific patient (Fig. 1, col. 2, lines 46-67, cols. 3-4 and col. 5, lines 1-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the Bunz components in a variety of sizes, i.e.,

provisional components, as taught by Fallin, so that the components can be custom fitted to a patient during a surgical procedure.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bunz (US 6,802,866) in view of McLean (US 2002/0116068).

Bunz discloses all the elements of the claimed invention except for the use of a polymer to construct either the male or the female junction elements.

McLean teaches the use of synthetic materials such as metals, ceramics or plastics to construct prosthetic components (para [0053]).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the Bunz components of metal and polymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pfaff et al. (US 6,607,560) in view of Fallin (US 5,108,452).

Pfaff et al. disclose all the elements of the claimed invention except for providing the components in a variety of sizes in kit form so that the components can be custom fitted to a patient during a surgical procedure.

Fallin teaches providing various prosthesis components in kit form so that a prosthesis can be custom fitted to a patient by a surgeon (Fig. 1 and col. 1, lines 12-39).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the Pfaff et al. components in a variety of sizes, i.e., provisional components, as taught by Fallin, so that the components can be custom fitted to a patient during a surgical procedure.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Averill et al. (US 4,921,500) in view of Fallin (US 5,108,452).

Averill et al. disclose all the elements of the claimed invention except for providing the components in a variety of sizes in kit form so that the components can be custom fitted to a patient during a surgical procedure.

Fallin teaches providing various prosthesis components in kit form so that a prosthesis can be custom fitted to a patient by a surgeon (Fig. 1 and col. 1, lines 12-39).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the Averill et al. components in a variety of sizes, i.e., provisional components, as taught by Fallin, so that the components can be custom fitted to a patient during a surgical procedure.

Response to Arguments

Applicants' arguments submitted under "REMARKS" in the response filed on January 18, 2007 have been fully considered

Regarding the rejections of claims 1, 3 and 4 as being anticipated by Pfaff et al., it is noted that the limitation "hollow, resilient sleeve capable of being rolled upon itself into a ring-like configuration" it is noted that the Pfaff et al. sleeve is capable of being rolled upon itself into a ring-like configuration. Pfaff et al. clearly disclose that sleeve 4 can have a structure that is like a woven fabric wherein the mode of weaving can influence the porosity and deformability of the fabric (col. 2, lines 22-44).

Applicants' arguments with respect to Averill et al. are not persuasive. Averill et al. clearly disclose that the male junction element 18 of the femoral stem and the female junction element 32 of the femoral head are directly engageable in a self-locking taper relationship when the femoral head and the femoral stem are made of metal. When the femoral head is made of ceramic and the femoral stem is made of metal, the sleeve will lock the head and the stem in "frictional relative position maintaining relationship."

Allowable Subject Matter

Claims 17-19 and 25 are allowed.

Claim 22 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
February 5, 2007

A handwritten signature in black ink, appearing to read "Anuadha Ramana". The signature is written in a cursive, flowing style.